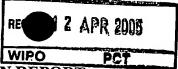
PONT COOPERATION TREATY PCT



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 686338C:MOB		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).		
International Application No.	International Filing Date (day/month/year)	Priority Date (day/month/year)		
PCT/AU2003/001688 18 December 2003 18 December 2002				
International Patent Classification (IPC) or	national classification and IPC			
Int. Cl. ⁷ A61K 39/12, 39/125, A61P	35/00			
Applicant THE UNIVERSITY OF NEWCA	ASTLE RESEARCH ASSO	CIATES LIMITED et al		
This international preliminary examination is transmitted to the applicant according	tion report has been prepared b g to Article 36.	y this International Preliminary Examining Authority and		
 This REPORT consists of a total of 5 This report is also accompanied to amended and are the basis for this 70.16 and Section 607 of the Adres 	by ANNEXES, i.e., sheets of the sreport and/or sheets containing	e description, claims and/or drawings which have been g rectifications made before this Authority (see Rule		
These annexes consist of a total of	nexes consist of a total of 8 sheet(s).			
3. This report contains indications relating to the following items:				
I X Basis of the report				
Π Priority .		,		
III Non-establishment of op	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability			
IV Lack of unity of inventio				
V X Reasoned statement under citations and explanation	er Article 35(2) with regard to a supporting such statement	ovelty, inventive step or industrial applicability;		
VI Certain documents cited				
VII Certain defects in the inte	Certain defects in the international application			
VIII X Certain observations on t	he international application			
Date of submission of the demand	Date of submission of the demand			
12 July 2004		completion of the report		
Name and mailing address of the IPEA/AU	Authori	ed Officer		
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRAL E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	M. On	g one No. (02) 6283 2491		

	E	Basis of the repor	t				
ι.	With	_	ard to the elements of the international application:*				
		the international	application as originally filed.				
	X	the description,	pages 1-13,16-36 as originally filed,				
			pages, filed with the demand,				
			pages 14,15 received on 4 March 2005 with the letter of 1 March 2005	Ì			
	X	the claims,	pages , as originally filed,				
	•	-	pages , as amended (together with any statement) under Article 19,				
			pages, filed with the demand,				
	الت		pages 37-42, received on 4 March 2005 with the letter of 1 March 2005				
	X	the drawings,	pages 1/19-19/19, as originally filed,				
			pages , filed with the demand,				
		the gamera line	pages, received on with the letter of				
		me sequence list	ing part of the description:				
			pages, as originally filed	1			
			pages , filed with the demand	•			
			pages, received on with the letter of	.2 ed to			
2.	With	regard to the lang	guage, all the elements marked above were available or furnished to this Authority in the language in				
	These	uich the international application was filed, unless otherwise indicated under this item. ese elements were available or furnished to this Authority in the following language which is:					
			translation furnished for the purposes of international search (under Rule 23.1(b)).	!			
		the language of publication of the international application (under Rule 48.3(b)).					
		the language of t and/or 55.3).	he translation furnished for the purposes of international preliminary examination (under Rules 55.2				
3.			eleotide and/or amino acid sequence disclosed in the international application, the international ation was carried out on the basis of the sequence listing:				
			international application in written form.				
	一	filed together with the international application in computer readable form.					
		furnished subsequently to this Authority in written form.					
	\Box	furnished subsequently to this Authority in computer readable form.					
		The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.					
			at the information recorded in computer readable form is identical to the written sequence listing has				
4.		The amendment	s have resulted in the cancellation of:				
		the desc	cription, pages				
		the clair	ms, Nos.				
		the drav	wings, sheets/fig.				
5.			neen established as if (some of) the amendments had not been made, since they have been considered isclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**	to			
*	Re		isclosure as med, as indicated in the Supplemental Box (Rule 70.2(c)). ** hich have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in th	uis.			
	rep	port as "originally f	iled" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).				
**	An	y replacement shee	t containing such amendments must be referred to under item 1 and annexed to this report				

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.	Statement		
	Novelty (N)	Claims 1-63	YES
		Claims	NO
	Inventive step (IS)	Claims 1-63	YES
	•	Claims	NO
	Industrial applicability (IA)	Claims 1-63	YES
		Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: Ferdat, AK et al D2: WO 2001/037866

D3: Taguchi, F

Novelty (N): Claims 1-63

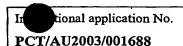
The invention is directed to the treatment of abnormal cells for example, cancerous cells, with an effective amount of an oncolytic virus selected from echoviruses and modified forms or combinations thereof, that recognises $\alpha_2\beta_1$ for the infectivity of the cells such that at least some of the cells are killed by the virus. The invention also encompasses the screening of abnormal cells for susceptibility to said virus and pharmaceutical compositions comprising the virus as an inoculant, together with a pharmaceutically acceptable carrier and the use thereof.

D1 teaches that the local administration of human echo-7 virus exerts an inhibitory effect on the growth of MX-17 tumour in BALB/c mice without signs of oncolysis. The document does not disclose nor suggest that at least some of the cells are killed by the virus.

D2 discloses a method of treating a malignancy for example, melanoma cells, with a virus that recognises a cell adhesion molecule and a complement regulatory protein, where the virus preferably is derived from the *Picornaviridae* family, e.g. coxsackievirus and echovirus. Specifically, the document discloses the use of echovirus type 7 (EV7) for infection of melanoma cells. However, the document does not disclose nor suggest that the virus recognise $\alpha_2\beta_1$ for the infectivity of the cells and eventual killing of the cells. It has been demonstrated by the applicant that EV7 infection involves the interaction of EV7 with the complementary regulatory protein, decay accelerating factor (DAF) not $\alpha_2\beta_1$.

D3 teaches the mass culture of viruses including echovirus that are used as inoculants for vaccines or antigens for diagnosis. However, it does not teach the killing of the abnormal cells. The document exemplifies only the preparation of smallpox vaccine liquor. Thus, it does not disclose all the essential features of the present invention.

Therefore the subject matter of these claims is new and meets the requirements of Article 33(2) PCT with regard to novelty.



Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of

Inventive Step (IS): Claims 1-63

Claims 1-63 meet the criteria set out in PCT Article 33(3) with regard to the requirement of Inventive Step because the prior art does not obviously suggest to a person skilled in the art to treat abnormal cells with echoviruses and modified forms that recognises $\alpha_2\beta_1$ for the infectivity of the cells and such that at least some of the cells are killed by the virus. With respect to D3 the applicant has distinguished the teachings of said document on the basis of the physicochemical and biological differences between the small pox virus and echovirus. On the basis of this, it is considered that the skilled addressee would not be directly led to prepare a pharmaceutical composition of echovirus of the present invention.

Industrial Applicability (IA) Claims 1-63

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 58-62 do not fully describe the invention. The claims are directed to an applicator comprising a region that is impregnated with an inoculant consisting of echovirus, modified forms or a combination thereof, that recognises $\alpha_2\beta_1$ for the infectivity of the cells. However, it appears from the applicant's response that an essential feature of the invention is that the inoculant kills at least some of the cells. This feature is not defined in the claims.

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